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Millennium™ Laser Photocoagulator System

510(k) SUMMARY
(per 21 CFR §807.92)

K022760

Submitter's Name:	Bausch & Lomb
Address:	3365 Tree Court Industrial Blvd. St. Louis, MO 63122
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Official Correspondent:	Dennis Pozzo Regulatory Affairs Specialist
Date Summary Prepared:	August 14, 2002 Revised - November 14, 2002
DEVICE NAME:	Millennium™ Laser Photocoagulator System
Classification/Common name:	Ophthalmic Laser Photocoagulator
Proprietary name:	Millennium™ Laser Photocoagulator System
Class:	II
Panel:	Ophthalmic
Product Code:	HQF

The marketed device(s) to which substantial equivalence is claimed:
IRIS Medical® OcuLight® GL Laser System
Millennium™ Microsurgical System

PRODUCT DESCRIPTION:

The Millennium™ Laser Photocoagulator System is a Class 4 laser. The system is made up of three separate components that are required to interface with each other in order to allow laser emission. They are the Laser Module, Multifunctional Foot Control with laser switch and the junction box. In order for the Millennium™ Microsurgical System to operate the Laser Module, the system must have laser enabled software. The software includes functions to recognize the laser module as a network node and provides the graphical user interface.

The interface performs any or all of the following functions:

- Display current laser photocoagulator operating parameters numerically.
- Display current laser photocoagulator operating status.
- Allow the surgical team to adjust laser photocoagulator operating set points and modes of operation.
- Provide audio feedback confirmation.
- All laser surgical interfaces shall appear readable while laser safety goggles are worn.

Two types of safety connections will be provided as part of the system:

1. a facility interlock,
2. a smart key safety filter sensing circuit.

A. Laser Module

The Laser Module contains an infrared semiconductor Continuous Wave (CW) diode laser light as the primary source of pump energy for the yttrium vanadate laser which is then wavelength converted to a visible green laser light for delivery to the patient's eye. A second visible red semiconductor CW laser is used for aiming. The treatment and pilot/aiming beams are optically combined inside the laser head and therefore, follow the same path.

The outer module housing consists of a front cover, chassis and chassis cover. The front cover provides mounting locations and access to the Laser Aperture, Laser Indirect Ophthalmoscope Illumination Connection, Key Switch, and Emergency Laser Stop Button.

The laser aperture is the distal end of the delivery device connected to the Laser Port on the module. The Laser Port is interlocked so that no laser energy can be emitted without the correct connection to a recognized delivery device. Since each type of delivery device has different losses due to varying optical components, the delivery device communicates electronically to the control system in the laser module. A transmission factor stored in the module's permanent memory calculates the power delivered out the delivery device and displays this calibrated value on the touch screen. This ensures accurate laser emission thus eliminating the need for user adjustment during calibration.

B. Multifunction Foot Controller with Laser Integrated Foot Switch

The Multifunctional Foot Controller connects to the Millennium™ Microsurgical System by an integral cord. The Multifunctional Foot Controller is watertight and corrosion resistant. The Multifunctional Foot Controller provides controls for the various modules and peripherals. It is comprised of a center foot pedal and five switches.

Center Pedal

The center pedal provides linear controls via pitch and yaw movements of the pedal. Each of the controls is fully programmable with respect to function and control parameter.

Switches

The Multifunctional Foot Controller has up to five buttons or switches. One of which is a dedicated laser switch. The four function switches are programmable to provide controls for all applicable Millennium™ Microsurgical System functions.

Laser Switch

The laser switch, when actuated, sends a laser-firing signal to the Laser Module. The laser switch is located at the base of the foot pedal. When the laser is to be fired, the cover is manually open. However, when the cover is open the switch still remains shrouded.

C. Laser Junction Box

The laser junction box is designed such that laser emission can not occur without it. The junction box connects to the foot switch via cabling, the cabling in combination with the box are the conduits through which the laser switch sends the laser firing signal to the Laser Module.

D. Laser Foot Switch

The Laser Foot Switch is dedicated only to firing the laser, it does not contain any other functional switches. It contains a safety shroud to protect against accidental activation, watertight switches and a dual redundant electrical safety system.

STATEMENT OF INDICATIONS FOR USE

The laser modes are intended for retinal photocoagulation and laser trabeculaplasty. Delivery devices available are the Endoprobe for intraocular endolaser surgery, and the Laser Indirect Ophthalmoscope Plus (LIO+) for transpupillary laser delivery for patients in the supine position.

SUBSTANTIAL EQUIVALENCE

The following is a comparison of the Millennium™ Laser Photocoagulator System to the IRIS Medical® OcuLight® GL Laser System.

The Millennium™ Laser Photocoagulator System is substantially equivalent to the IRIS Medical® OcuLight® GL Laser System produced by the IRIDEX Corporation in that both are semiconductor based continuous wave green light lasers to be used for retinal photocoagulation.

Similarities

- Both the Millennium™ Laser Photocoagulator System and the OcuLight® GL Laser System are intended for retinal photocoagulation procedures.
- Both the Millennium™ Laser Photocoagulator System and the OcuLight® GL Laser System contain an infrared (808 nm) semiconductor continuous wave diode as its primary source of optical energy.
- Both the Millennium™ Laser Photocoagulator System and the OcuLight® GL Laser System use treatment laser beams that are generated in the identical optical cascade.
- Both the Millennium™ Laser Photocoagulator System and the OcuLight® GL Laser System use the identical EndoProbe® and Laser Indirect Ophthalmoscope Plus as laser delivery devices.

Differences

- The Millennium™ Laser Photocoagulator System is a modular system.
- The OcuLight® GL Laser System is a complete integrated laser system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Bausch & Lomb
Dennis Pozzo
Regulatory Affairs Specialist
3365 Tree Court Industrial Boulevard
St. Louis, Missouri 63122

Re: K022760
Trade/Device Name: Millennium™ Laser Photocoagulator System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 19, 2002
Received: August 20, 2002

Dear Mr. Pozzo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number - K022760

Device Name: Millennium Laser Photocoagulator System

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Division Sign-Off)

510(k) Number K022760

Bausch & Lomb Surgical

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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